

1. (Original) A sample collection device for collecting a biological sample from a mammary organ of a patient, comprising:

- a breast engaging member constructed of a non-porous material sized and dimensioned to receive at least a nipple portion of a breast of said patient and form a suction seal therewith;
- a solid phase sample collection medium in fluid connection with said breast engaging member for receiving a sample of expressed breast fluid; and
- vacuum pump means in gaseous connection with said breast engaging member for generating negative pressure through the breast engaging member to facilitate breast fluid expression, wherein the sample collection device is a hand-held breast pump incorporating said breast engaging member and vacuum pump means in a compact, structurally integrated breast fluid collection apparatus that can be manipulated and operated with one hand.

2. (Original) The sample collection device of claim 1, wherein said solid phase sample collection medium is selected from the group consisting of microscopic glass slides, capillary tubes, collection tubes, columns, micro-columns, wells, plates, membranes, filters, resins, inorganic matrices, beads, resins, particulate chromatographic media, plastic microparticles, latex particles, coated tubes, coated templates, coated beads, coated matrices, or a combination thereof.

3. (Currently Amended) The sample collection device of claim 1, wherein said hand-held breast pump comprises a modular device formed of a plurality of components that are joined or securable in fixed structural interconnection with one another and may be adapted to

be partially or completely disassembled to remove or uncouple the individual components as desired for efficient operation, cleaning, servicing and/or storage.

4. (Currently Amended) The sample collection device of claim 3, wherein said ~~modular breast pump device includes~~ the breast engaging member is a separate breast engaging member constructed of a rigid ~~or semi-rigid~~, non-porous material sized and dimensioned to receive at least a nipple or areolar portion of a human subject's breast and form a suction seal therewith, wherein said breast engaging member is detachable from one or more interconnecting components of the hand-held pump device for cleaning and sterilization or to allow for interchanging of different engaging members to accommodate breast anatomy differences among patients.

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5. (Original) The sample collection device of claim 1, wherein said solid phase sample collection medium is supported by a support member removably mounted in fluid connection with said breast engaging member.

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6. (Currently Amended) The sample collection device of claim 5, wherein said support member is provided as a removable cassette that is adapted to ~~can~~ be inserted within said breast engaging member to be removably mounted in fluid connection therewith.

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α5 7. (Currently Amended) The sample collection device of claim 5, wherein said support member supports one or more ~~pads or~~ sheets of absorbent or adsorbent material.

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8. (Original) The sample collection device of claim 1, wherein said solid phase sample collection medium comprises a nitrocellulose membrane.

9. (Original) The sample collection device of claim 8, wherein said nitrocellulose membrane has a pore size selected to effectively retain whole cells from expressed breast fluid on a surface of the membrane.

10. <sup>Amended</sup>~~(Original)~~ The sample collection device of claim 7, wherein the ~~pad or~~ sheet is a modified membrane or filter having perforations or slits that disrupt the planar surface of the membrane or filter to facilitate air passage therethrough and impart structural flexibility against mechanical perturbation.

11. (Currently Amended) The sample collection device of claim 5, wherein said support member incorporates one or more air channels that pass through a body of the support member for passage of vacuum pressure therethrough and ~~and/or~~ to serve as channels for passage ~~or of~~ breast fluid sample materials between the breast engaging member and a sample collection housing member of the hand-held breast pump.

12. (Currently Amended) The sample collection device of claim 1, further comprising a sample collection housing member and a fluid-retaining ~~recess~~, well ~~or reservoir~~ integrated or fluidly connected with ~~the~~ a support member of ~~or a~~ the sample collection housing member ~~of the hand held pump device~~.

ab 13. (Currently Amended) The sample collection device of claim 12, wherein the fluid-retaining ~~recess~~, well ~~or reservoir~~ comprises an integral, defined compartment or enclosure within the sample collection housing for receipt of breast fluid and/or constituent samples thereof

14. (Currently Amended) The sample collection device of claim 12, wherein the fluid-retaining ~~recess~~, well ~~or reservoir~~ comprises a removable fluid reservoir member of the sample collection housing.

15. (Currently Amended) The sample collection device of claim 14, wherein the removable reservoir member is a rigid sample collection tube ~~or vial~~ removably connected with an outer casing member of the housing that partially or completely encloses the tube or vial.

16. (Currently Amended) The sample collection device of claim 14, wherein the removable reservoir member is a rigid sample collection tube ~~or vial~~ removably, sealably connected with an outer casing member of the housing to form an airtight coupling therewith.

17. (Original) The sample collection device of claim 14, wherein the removable reservoir member is a cytology vial sealably connected with an outer casing member of the housing to form an airtight coupling therewith.

18. (Currently Amended) The sample collection device of claim 17, wherein the removable reservoir member and outer casing member of the housing are coupled to form an assembled sample collection housing, wherein the reservoir member is removably nested within the casing member to form a substantially airtight contact between an inner wall of the casing member wall and an outer wall, ~~or a top or bottom end,~~ of the reservoir member.

19. <sup>Amended</sup>  
(Original) The sample collection device of claim 18, wherein an outer wall of the removable reservoir member features a circumferential ~~ridge, fin or~~ O-ring that engages and makes a circumferential airtight seal against the inner wall of the casing member when the vial is nested within the casing member.

20. (Original) The sample collection device of claim 14, wherein the removable reservoir member is gaseously and fluidly connected with the breast engaging member to facilitate sample collection.

21. (Original) The sample collection device of claim 14, wherein vacuum pressure from the vacuum pump means is routed to the breast engaging member through the removable reservoir member of the housing.

22. (Original) The sample collection device of claim 21, wherein the removable reservoir member is modified to include one or more air ports that form a gaseous connection between a lumen of the reservoir and the vacuum pump means.

as 23. (Currently Amended) The sample collection device of claim 14, wherein the removable reservoir member functions as both a conduit for vacuum pressure transmission to the breast and a receptacle for fluid sample materials ~~to directly collect expressed fluid or as a secondary collection medium to receive primarily collected sample materials washed or otherwise transferred from a primary solid phase sample collection medium.~~

24. ~~(Original)~~ <sup>Amended</sup> The sample collection device of claim 14, further comprising a support member coupled with the breast engaging member, wherein the removable reservoir member communicates for fluid and gaseous transmission directly with the breast engaging member ~~or indirectly therewith by way of air channels in a the support member optionally coupled with the breast engaging member.~~

ag 25. (Currently Amended) The sample collection device of claim 14, wherein a primary ~~the~~ solid phase sample collection medium fluidly connected with the breast engaging member is positioned to collect a primary sample of one or more breast fluid components which can thereafter be washed or otherwise transferred directly or indirectly into the removable reservoir member without removal or disassembly of the breast engaging member and reservoir member.

26. (Original) The sample collection device of claim 25, wherein the primary solid phase sample collection medium is a nitrocellulose membrane for retaining cells and other cytological materials on a surface of the membrane.

27. (Original) The sample collection device of claim 25, wherein the primary sample collection medium is supported in fluid connection with the breast engaging member by a support member, and wherein the support member includes one or more sample transfer channels for transfer of the primary sample from the primary collection medium, through the channels into the removable reservoir.

a10 28. (Currently Amended) The sample collection device of claim 27, wherein the sample transfer channels extend through ~~tubular basal columns or other fluid~~ connection ports that extend from the support member toward, or into, a lumen of the fluid reservoir member.

29. (Original) The sample collection device of claim 14, wherein the removable reservoir member is a cytology vial having one or more air ports that communicate between an outer wall and inner lumen of the vial to form a gaseous connection between the lumen of the vial, the vacuum pump means, and the breast engaging member.

a11 30. (Currently Amended) The sample collection device of claim 14, wherein the removable reservoir member further comprises closure means for closing ~~closure of~~ the reservoir after sample collection is completed to prevent sample contamination and spillage, whereby the removable reservoir member serves a multi-purpose function for sample collection as a component of the breast pump device as well as for storage, transport and/or processing of the sample upon removal of the reservoir member from the device.

31. (Original) The sample collection device of claim 30, wherein the closure means comprises a cap adapted to sealably engage a top end of the removable reservoir member.

a12 32. (Currently Amended) The sample collection device of claim 30, wherein the reservoir member is modified to include one or more air ports that form a gaseous connection between a lumen of the reservoir member and the vacuum pump means when the reservoir member is engaged with the pump device, and wherein the closure means further comprises secondary closure means to sealably close the one or more air ports ~~air port(s)~~ after sample collection.

33. (Original) The sample collection device of claim 32, wherein said secondary closure means comprise an adhesive seal or sticker sized and constructed to adhere to an outer wall of the reservoir member surrounding an air port opening.

34. (Currently Amended) The sample collection device of claim 32, wherein said secondary closure means comprises a combined closure and labeling device which functions as a secondary closure mechanism to seal the one or more air ports ~~air port(s)~~ of the removable reservoir member and as a labeling template to provide a writing surface for sample labeling.

35. (Currently Amended) The sample collection device of claim 32, wherein said secondary closure means comprises a combined closure and labeling tab or sticker which ~~may~~ is adapted to be directly applied to seal the one or more air ports ~~air port~~ after sample collection having a first, closure-forming surface for application over the air port to form a seal by juxtaposition or adhesive contact with an outer wall of the removable reservoir member, and a second, labeling surface opposite the closure-forming surface made of a blank template material suitable for receiving a stable, ink or graphite imprint thereon.

36. (Original) The sample collection device of claim 35, wherein said first, closure-forming surface bears an adhesive coating resistant to disruption by contact with aqueous solutions.

37. (Currently Amended) The sample collection device of claim 32, wherein said secondary closure means comprises a combined closure and labeling tab or sticker which is pre-attached to the removable reservoir member in a first, open configuration and ~~can~~ is adapted to be manually repositioned ~~or otherwise manipulated~~ after sample collection to a second, closed configuration to form a seal or closure against the one or more air ports ~~air port(s)~~.

38. (Currently Amended) The sample collection device of claim 37, wherein said secondary closure means comprises an adhesive tab or strip folded in the open configuration to form an inner layer affixed to the reservoir proximate to the air port and an outer layer folded over the inner layer, said outer layer providing ~~the~~ a first, closure-forming surface and ~~the~~ a second, labeling surface, wherein the outer layer can be unfolded away from the inner layer and wrapped around the reservoir member so that the closure-forming surface covers the ~~air port~~ one

2-15 or more air ports to form a fluid-resistant closure and the labeling surface faces outward for recordation of sample data.

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39. (Original) The sample collection device of claim 38, wherein the outer layer is optionally secured in a folded-back position against the inner layer by adhesive engagement of the labeling surface with the inner layer.

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40. (Currently Amended) The sample collection device of claim 39, wherein said first, closure-forming surface bears an adhesive coating that is protected in the open configuration by folding of an end segment of the outer layer bearing the adhesive coating back, so that the closure forming surface provides a protective surface to shield the adhesive prior to closure, whereby the end segment is adapted to ~~can~~ be lifted and pulled outward to unfold the end segment to separate the adhesive coating on the closure-forming surface from the protective surface and to release the outer layer from the inner layer for closing of the one or more air ports air port(s).

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41. (Original) The sample collection device of claim 14, wherein the breast engaging member includes removable coupling means for removable coupling of the breast engaging member with a complementary coupling surface of the sample collection housing.

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42. (Currently Amended) The sample collection device of claim 41, wherein the sample collection housing includes an outer casing member and a removable, fluid reservoir member, and wherein the breast engaging member ~~can~~ is adapted to be directly coupled to the fluid reservoir member.

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43. (Currently Amended) The sample collection device of claim 42, wherein the breast engaging member has coupling threads to engage complementary threads of an open end of the removable reservoir member, said complementary threads of the reservoir adapted to interchangeably receive a cap that sealably engages the reservoir open end.

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44. (Original) The sample collection device of claim 43, wherein the removable reservoir member is a modified cytology vial.

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a<sub>18</sub> 45. (Currently Amended) The sample collection device of claim 1, further comprising a sample collection housing, wherein the solid phase sample collection medium is adjustably mounted relative to the sample collection housing so that the solid phase collection medium can be controllably moved closer to, or farther away from, a base of the breast engaging member of the pump sample collection device during use.

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46. (Original) The sample collection device of claim 1, further comprising a reciprocating mechanism which adjustably moves the solid phase sample collection medium in closer, or more distant, proximity to the nipple when the hand-held breast pump is engaged therewith.

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47. (Currently Amended) The sample collection device of claim 1, further comprising a compact vacuum pump housing which structurally and functionally integrates the vacuum pump means with the sample collection housing.

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a<sub>19</sub> 48. (Currently Amended) The sample collection device of claim 47, further comprising a sample collection housing, wherein the vacuum pump housing and outer casing member of the sample collection housing are cast or molded as a single, integral component of the device.

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49. (Original) The sample collection device of claim 1, further comprising a vacuum pump actuating mechanism connected to a vacuum pump housing of the device.

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a<sub>20</sub> 50. (Currently Amended) The sample collection device of claim 49, wherein the vacuum pump actuating mechanism comprises an actuating lever pivotally connected to the vacuum pump housing.

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51. (Currently Amended) The sample collection device of claim 49, wherein the vacuum pump housing includes an integral handle opposing an actuating lever pivotally connected to a base portion of the handle.

52. (Currently Amended) The sample collection device of claim 1, further comprising a sample collection housing, wherein the vacuum pump means comprises a flexible diaphragm member and pump actuating ~~actuation~~ means to draw the diaphragm member away from a primary vacuum chamber connected with, or integrated within, the sample collection housing.

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53. (Original) The sample collection device of claim 52, further comprising a vacuum pump housing, wherein the primary vacuum chamber is integrally formed within the vacuum pump housing proximate the flexible diaphragm member and extends to a communicating port opening to the sample collection housing.

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54. (Currently Amended) The sample collection device of claim 53, further comprising a removable fluid reservoir member of the sample collection housing modified to include one or more air ports that form a gaseous connection between a lumen of the reservoir member and the communication port to gaseously connect the lumen of the reservoir member to the primary vacuum chamber.

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